REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-21 are in this case. Claims 1, 2, 6, 7 and 10-16 have been rejected under § 102(b) or § 103(a). Claims 3-5, 8, 9 and 17-21 have been objected to. Independent claims 1 and 14 and dependent claim 18 have been amended.

The claims before the Examiner are directed toward a device and method for detecting malfunction of a gravity fed intravenous delivery system by sensing reversal of a direction of pressure difference between ambient atmospheric pressure and the fluid inside the tubing at a location where the pressure of the fluid is normally below atmospheric pressure. In contrast to the arbitrary pressure thresholds used by the prior art, this objective and well defined criterion ensures reliable and sensitive detection of a malfunction condition.

Objections to the Drawings

The Examiner has objected to the drawings for various informalities. Specifically, the Examiner has pointed out the omission of reference numerals 38, 40 and 72 from the drawings.

The Applicant submits herewith a proposed drawing correction and replacement pages of drawings (Figures 2 and 3a-3c) adding the omitted reference numerals. The Applicant believes that the Examiner's objections have been fully addressed by the changes made. Formal drawing will duly be filed in due course.

Objections to the Specification

The Examiner has objected to the specification for various informalities. Specifically, the Examiner has pointed out that the abstract contains a typographical

error which resulted in the repetition of the phrase "an accurate". A replacement abstract is supplied herewith in which this error has been corrected.

The Examiner has also pointed out that the reference on page 18 lines 18-19 to "Figure 4" should read --Figure 6--, and the reference on page 18 line 21 to "Figure 6" should read --Figure 7--. These errors have now been corrected as indicated by the Examiner.

The Applicant believes that the specification is now free from the informalities identified by the Examiner.

Claim Formalities

It has come to the Applicant's attention that claim 18 was erroneously indicated to be dependent directly from claim 14, thereby lacking sufficient antecedent basis for the "electrical contacts". Claim 18 has now been amended to depend from claim 17, thereby resolving this issue.

§ 102(b) & § 103(a) Rejections

The Examiner has rejected claims 1, 2, 6 and 7 under § 102(b) as being anticipated by Singh et al. (US 4784648). The Examiner has further rejected claims 10-13 under § 103(a) as being unpatentable over Singh et al. in view of Atkins et al. (US 4877034). Finally, the Examiner has rejected claims 14-16 under § 103(a) as being unpatentable over Singh et al. in view of Olson (US 3901231). The Examiner's rejections are respectfully traversed.

Singh et al. teaches an infiltration indicator and alarm for use in a high-driving-pressure infusion system. The system uses a constant high-pressure pump together with a fixed flow restriction to define the flow rate. A first region of elastomeric tubing upstream of a flow constriction configured to inflate at a pressure

threshold in the range of 200-500 Torr to show proper operation of the pump, and a second region of elastomeric tubing downstream of the flow constriction configured to inflate at a pressure threshold in the range of 35 to 110 Torr to provide an indication of infiltration.

It should be noted that the infiltration sensor of Singh et al. can only operate reliably in the specific situation described, namely, with a high-pressure source and fixed flow restriction. In such a case, as long as the flow restriction is the primary flow impedance of the infusion system, the pressure on the downstream side of the restriction is low and substantially constant, whereas if an additional flow obstruction occurs further downstream, the pressure downstream of the flow restriction starts to equalize with the upstream pressure. Given that the upstream supply pressure is in the 200-500 Torr range, the pressure in the downstream tubing can quickly reach values much higher than the normal working pressures, e.g., up to 110 Torr as mentioned, which are sensed by the second elastomeric tube.

Olson discloses a pump apparatus for delivering an infusion. The apparatus includes a pressure sensor which triggers a warning light under "overpressure" condition. Here too, the "overpressure" condition is clearly an elevated pressure threshold which may be reached in the case that the infusion pump operates under blockage conditions.

In contrast, in a gravity-fed infusion set, the very much lower supply pressure results in much less pronounced pressure changes under infiltration conditions. As discussed in the Background of the Invention (page 2 lines 1-11):

> **Several methods ... have been proposed for the detection of tissue infiltration during intravenous administration of fluids. One approach is by monitoring the flow rate or pressure of fluid in the tubing supplying the fluid to the catheter. ... Commercially available device based on these**

> **techniques, however, are generally ineffective since the pressure differences indicative of extravasation are typically small in relation to other causes of pressure variations in an intravenous delivery system during use, such as patient movements or changes in the head pressure of an infusion bag.**

In other words, the small pressure variations occurring as a result of infiltration in a gravity-fed infusion set are typically of similar magnitude to pressure variations caused by numerous other causes. As a result, sensing whether the pressure exceeds a defined threshold value cannot provide reliable infiltration detection.

In contrast to the quantitative threshold criterion of the prior art, the method and device of the present invention employ a qualitative criterion, namely, the reversal of direction of a pressure difference, to reliably detect infiltration in a gravity-fed infusion set. Specifically, the present invention senses reversal of a direction of pressure difference between ambient atmospheric pressure and the fluid inside the tubing at a location where the pressure of the fluid is normally below atmospheric pressure. This objective and well defined criterion ensures reliable and sensitive detection of a malfunction condition, and avoids the need for any calibration.

While continuing to traverse the Examiner's rejections, the Applicant has, in order to expedite the prosecution, chosen to amend independent claims 1 and 14 in order to clarify and emphasize the crucial distinctions between the device of the present invention and the devices of the patents cited by the Examiner. Specifically, claim 1 has been amended to clarify that the sheath is configured such that, when a fluid pressure within the interior flow passage is less than atmospheric pressure, the sheath is pressed against the housing and, when a fluid pressure within the interior flow passage rises above atmospheric pressure, the sheath expands.

Similarly, independent claim 14 has been amended to further emphasize that the method of the present invention includes monitoring a direction of pressure

difference between ambient atmospheric pressure and the fluid inside the tubing, said direction of pressure difference being monitored at a location chosen such that, during normal operation of the gravity fed intravenous delivery system, the pressure of the fluid is normally below atmospheric pressure.

Support for these amendments can be found in the specification, and specifically, on page 15 lines 5-8 and 14-22, and on page 16 lines 20-22.

Amended independent claims 1 and 14 now feature language which makes it absolutely clear that the device of the present invention identifies infiltration by sensing reversal of a direction of pressure difference between ambient atmospheric pressure and the fluid inside the tubing. The Applicant believes that the amendment of the claims completely overcomes the Examiner's rejections on § 102(b) and § 103(a) grounds.

Objections

The Examiner has objected to claims 3-5, 8, 9 and 17-21 as being based on rejected base claims. The Examiner has noted that these claims would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claim.

In view of the discussion above in the context of the § 102(b) and § 103(a) rejections, the Applicant submits that the base claims from which these claims depend are allowable, making these claims allowable in their present form.

In view of the above amendments and remarks it is respectfully submitted that independent claims 1 and 14, and hence also dependent claims 2-13 and 15-21, are in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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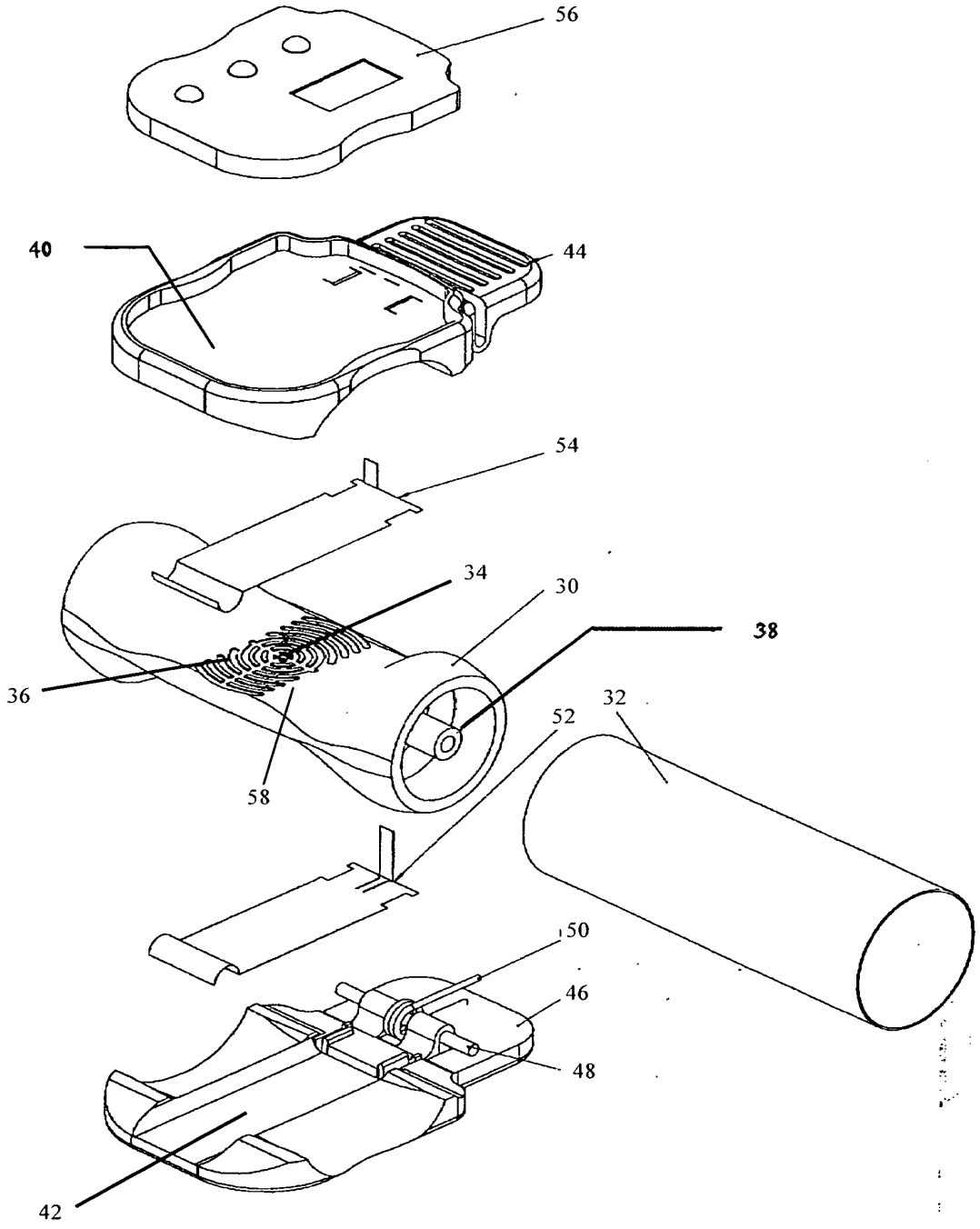

FIG. 2

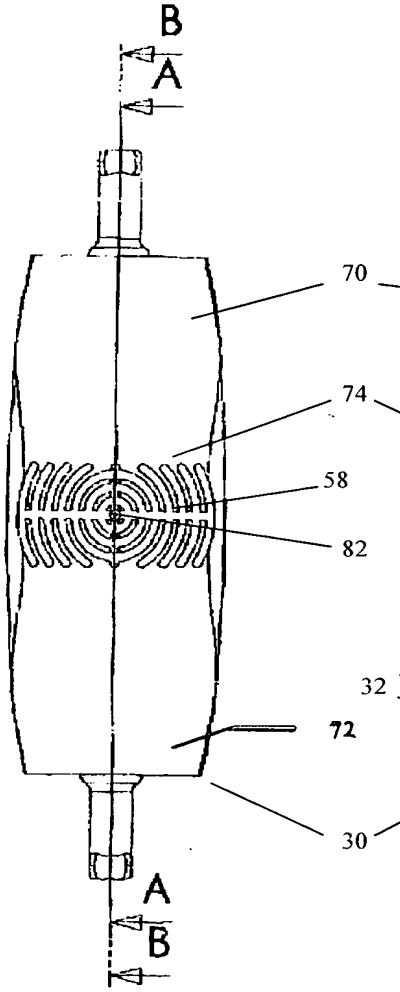

FIG.3a

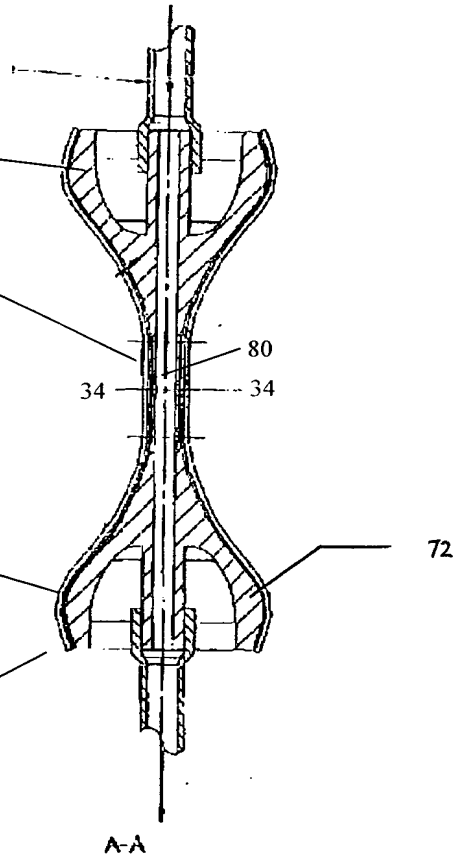

FIG 3b

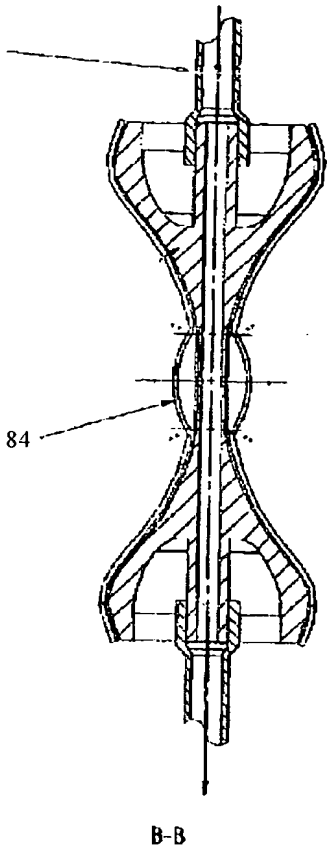

FIG. 3c